



General Assembly

February Session, 2016

Raised Bill No. 5270

LCO No. 1144



Referred to Committee on PUBLIC HEALTH

Introduced by:
(PH)

AN ACT CONCERNING THE RIGHT TO TRY EXPERIMENTAL DRUGS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (*Effective October 1, 2016*) (a) For purposes of this
2 section and sections 2 to 5, inclusive, of this act:

3 (1) "Investigational drug, biological product or device" means a
4 drug, biological product or biological device that has successfully
5 completed phase one of a clinical trial but has not yet been approved
6 for general use by the federal Food and Drug Administration and
7 remains under investigation in a clinical trial approved by the federal
8 Food and Drug Administration.

9 (2) "Patient" means a person who has a terminal illness, verified by
10 the patient's treating physician, and is not being treated as an inpatient
11 in a hospital licensed under chapter 368v of the general statutes.

12 (3) "Treating physician" means a physician licensed under chapter
13 370 of the general statutes who has primary responsibility for the
14 medical care of the patient and treatment of the patient's terminal

15 illness.

16 (4) "Terminal illness" means a medical condition that a patient's
17 treating physician anticipates, with reasonable medical judgment, will
18 result in a patient's death or a state of permanent unconsciousness
19 from which recovery is unlikely within a period of one year.

20 (b) A patient is eligible to receive treatment with an investigational
21 drug, biological product or device if the patient has (1) considered all
22 other treatment options currently approved by the federal Food and
23 Drug Administration, (2) been unable to participate in a clinical trial
24 for the terminal illness not more than one hundred miles from the
25 patient's home address, or not been accepted to a clinical trial not more
26 than one week after completion of the clinical trial application process,
27 (3) received a recommendation from his or her treating physician for
28 an investigational drug, biological product or device, (4) given written,
29 informed consent, as provided in subsection (c) of this section, for the
30 use of the investigational drug, biological product or device or, if the
31 patient is a minor or lacks the mental capacity to provide informed
32 consent, a parent of the minor or a legal guardian of the minor or adult
33 patient has given such written, informed consent on the patient's
34 behalf, and (5) written documentation from his or her treating
35 physician stating that the patient meets the requirements of this
36 subsection.

37 (c) A patient gives written informed consent when the patient, or if
38 the patient is a minor or lacks the mental capacity to provide informed
39 consent, a parent of the minor or the legal guardian of the minor or
40 adult patient, signs a written document, verified by the patient's
41 treating physician and a witness that at a minimum: (1) Explains the
42 currently approved products and treatments for the terminal illness
43 from which the patient suffers; (2) verifies the fact that the patient
44 concurs with his or her treating physician in believing that all currently
45 approved and conventionally recognized treatments are unlikely to
46 prolong the patient's life; (3) clearly identifies the specific proposed

47 investigational drug, biological product or device with which the
48 patient is seeking to be treated; (4) describes the potentially best and
49 worst outcomes of using the investigational drug, biological product or
50 device with a realistic description of the most likely outcome,
51 including the possibility that new, unanticipated, different or worse
52 symptoms might result and that death could be hastened by the
53 proposed treatment based on the treating physician's knowledge of the
54 proposed treatment in conjunction with an awareness of the patient's
55 condition; (5) states clearly that the patient's health carrier, as defined
56 in section 38a-477aa of the general statutes, treating physician or other
57 health care provider is not obligated to pay for any care or treatments
58 resulting from the use of the investigational drug, biological product
59 or device; (6) states clearly that the patient's eligibility for hospice care
60 may be withdrawn if the patient begins treatment with an
61 investigational drug, biological product or device, but that hospice
62 care may be reinstated if such treatment ends and the patient meets
63 hospice eligibility requirements; (7) states clearly that in-home health
64 care may be denied if such treatment begins; and (8) states that the
65 patient understands that the patient is liable for all expenses resulting
66 from the use of the investigational drug, biological product or device
67 and that this liability extends to the patient's estate, unless a contract
68 between the patient and the manufacturer of the drug, biological
69 product or device states otherwise.

70 Sec. 2. (NEW) (*Effective October 1, 2016*) A manufacturer of an
71 investigational drug, biological product or device may make available
72 the manufacturer's investigational drug, biological product or device
73 to a patient, who is eligible under subsection (b) of section 1 of this act,
74 and may (1) provide the investigational drug, biological product or
75 device to such patient without receiving compensation, or (2) require
76 such patient to pay the costs of, or associated with, the manufacture of
77 the investigational drug, biological product or device.

78 Sec. 3. (NEW) (*Effective October 1, 2016*) (a) A health carrier, as
79 defined in section 38a-477aa of the general statutes, may provide

80 coverage for the cost of an investigational drug, biological product or
81 device made available, pursuant to section 2 of this act, to a patient
82 who is eligible under subsection (b) of section 1 of this act.

83 (b) A health carrier may deny coverage to such patient from the
84 time such patient begins treatment with the investigational drug,
85 biological product or device for a period not to exceed six months from
86 the date such patient ceases treatment with the investigational drug,
87 biological product or device, except coverage may not be denied for a
88 preexisting condition or for coverage for benefits that commenced
89 prior to the date such patient begins such treatment.

90 (c) Nothing in this section shall affect the provisions of sections 38a-
91 504a to 38a-504g, inclusive, and 38a-542a to 38a-542g, inclusive, of the
92 general statutes concerning insurance coverage for certain costs
93 associated with clinical trials. Treatment with an investigational drug,
94 biological product or device pursuant to sections 1 to 5, inclusive, of
95 this act is not considered a clinical trial for purposes of said sections.

96 Sec. 4. (NEW) (*Effective October 1, 2016*) (a) Notwithstanding the
97 provisions of chapter 370 of the general statutes, the Department of
98 Public Health or the Connecticut Medical Examining Board shall not
99 revoke, fail to renew, suspend or take any disciplinary action against a
100 physician based solely on the treating physician's recommendation to a
101 patient regarding access to, or treatment with, an investigational drug,
102 biological product or device, provided such recommendation is
103 consistent with medical standards of care.

104 (b) No official, employee or agent of the state shall prevent, or
105 attempt to prevent, a patient who is eligible under subsection (b) of
106 section 1 of this act from accessing an investigational drug, biological
107 product or device.

108 Sec. 5. (NEW) (*Effective October 1, 2016*) Nothing in sections 1 to 4,
109 inclusive, of this act shall create a private cause of action against a
110 manufacturer of an investigational drug, biological product or device

111 or against the patient's treating physician or any other person or entity
112 involved in the care of a patient being treated with an investigational
113 drug, biological product or device for any harm done to such patient
114 resulting from the investigational drug, biological product or device.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2016</i>	New section
Sec. 2	<i>October 1, 2016</i>	New section
Sec. 3	<i>October 1, 2016</i>	New section
Sec. 4	<i>October 1, 2016</i>	New section
Sec. 5	<i>October 1, 2016</i>	New section

Statement of Purpose:

To allow eligible patients to try investigational drugs, biological products or devices.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]